**SITE VISIT REPORT FORM**

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| **MCU-FDTMF IRB PROTOCOL CODE** |  | **Date of the Visit** |  |

|  |  |
| --- | --- |
| **Protocol Title** |  |

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| --- | --- | --- | --- |
| **Name** |  | **Email** | **Mobile / Phone / Fax Number** |
| **Principal Investigator** |  |  |  |
| **Sponsor** |  |  |  |

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| **Reason for the visit** |  | | |
| **Person/s interviewed** |  | | |
| **Total number of expected subjects** |  | **Total subjects enrolled** |  |

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|  | **Yes** | | | **No** | | | **Comments** |
| 1. Are site facilities appropriate? |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |
| 1. Is confidentiality of documents maintained (e.g., cabinets with lock and keys)? |  |  |  |  |  |  |  |
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| 1. Are the test articles properly kept and maintained? |  |  |  |  |  |  |  |
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| 1. Are informed Consent Forms completed? |  |  |  |  |  |  |  |
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| 1. Are approved current ICF version used? |  |  |  |  |  |  |  |
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| 1. Are copies of the approved versions of the protocol documents kept in the site? |  |  |  |  |  |  |  |
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| 1. Are files of all communications with the MCU-FDTMF IRB found in the study site? |  |  |  |  |  |  |  |
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| 1. Are copies of adverse event report kept? |  |  |  |  |  |  |  |
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| 1. Are investigator functions properly delegated to qualified research personnel? |  |  |  |  |  |  |  |
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| 1. Is there appropriate documentation of qualifications of personnel? |  |  |  |  |  |  |  |
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| 1. Are all Case Record Forms up to date? |  |  |  |  |  |  |  |
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| 1. Are copies of protocol non-compliance (violation/deviation) reports kept in the study site? |  | | | | | |  |
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| 1. Is there evidence of appropriate corrective action taken as recommended by the MCU-FDTMF IRB? |  |  |  |  |  |  |  |
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| **Site Visit Team Conclusions/Recommendations**: | | | | | | | |

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| **Duration of Visit (in hours)** |  | **Time Started** |  | **Time Finished** |  |

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|  | **Name and Signature** | **Date** |
| **MCU-FDTMF Site Visit Team**  **Members/Secretariat Staff** |  |  |
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| **Report prepared by** |  |  |
| **Noted by:**  **Site Visit Team Leader** |  |  |

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| **MCU-FDTMF IRB Decision** |  |  |  |  |
|  |  |  | No further action |
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|  |  |  | Request additional information, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |
|  |  |  | Recommend further action, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **MCU-FDTMF IRB Chair** | **Signature** | **Date** |
|  |  |  |